K111165
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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of KSEA's knowledge.

JAN - 6 2012

Submitter: Karl Storz Endoscopy-America, Inc.
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Contact Person: Crystal Hagan
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Date Prepared: April 25, 2011

Device Trade Name: Karl Storz SCB/Covidien ForceTriad Interface Module

Common Name: Endoscope and/or accessories

Classification Name: Endoscopic central control unit

Regulation Number: 21 CFR 876.1500

Product Code: ODA

Predicate Device(s):
Karl Storz SCB/ConMed ESU Interface Module (K080410)

Device Description:
The Karl Storz SCB/Covidien ForceTriad Interface Module is an accessory to integrate the third party device Covidien ForceTriad Energy Platform (K102913) into the SCB network and allow remote settings adjustment.

Intended Use:
The KARL STORZ SCB/Covidien ForceTriad Interface Module is designed for integration in the SCB Interface Control, SCB Media Control or ACC Control and enables the COVIDIEN ForceTriad Energy Platform to be controlled remotely with the KARL STORZ SCB control NEO system.

Technological Characteristics:
The "module" is an accessory which is installed and housed within a Karl Storz SCB control device (Interface Control, Media Control or ACC Control). The SCB control device is connected to the Covidien ForceTriad Energy Platform via an RS232 connection. Once installed, the Karl Storz SCB/Covidien ForceTriad Interface Module allows the user interface of the ForceTriad Energy Platform to be displayed on the SCB R-UI. Device settings of the Covidien ForceTriad Energy Platform can be remotely adjusted via the SCB-RUI. For a summary of technological characteristics of the Karl Storz SCB/Covidien ForceTriad Interface Module as compared to the predicate device, please refer to the attached substantial equivalence table.

Software Testing:
The Karl Storz SCB/Covidien ForceTriad Interface Module demonstrated performance equivalence by software verification and validation testing, in which the device was installed into the SCB control device and the system's ability to interface with the Covidien ForceTriad Energy Platform was tested. The performance of the Karl Storz SCB/Covidien ForceTriad Interface Module was found to be substantially equivalent to the predicate Karl Storz SCB/ConMed ESU Interface Module.

Determination of Substantial Equivalence:
The Karl Storz SCB/Covidien ForceTriad Interface Module is substantially equivalent to the predicate device, as both devices have the same intended use and basic design. The differences between the SCB/Covidien ForceTriad Interface Module and the predicate device are minor and raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or general intended use of these devices.

Conclusions:
The Karl Storz Scalp Dura Retractor is substantially equivalent to the identified predicate devices and does not raise any new issues of safety and efficacy.

Att: Substantial Equivalence Table for Karl Storz SCB/Covidien ForceTriad Interface Module

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Ankit Shah
Regulatory Affairs Associate
Karl Storz Endoscopy-America, Inc.
2151 E. Grand Avenue
EL SEGUNDO CA 90245

JAN - 6 2012

Re: K111165
Trade/Device Name: Karl Storz SCB/Covidien Force Triad Interface Module
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODA
Dated: December 8, 2011
Received: December 9, 2011

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D., Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K111165

INDICATIONS FOR USE

510(k) Number (if known): ~~Not yet assigned~~ K111165

Device Name: Karl Storz SCB/Covidien ForceTriad Interface Module

Indications for Use: The KARL STORZ SCB/Covidien ForceTriad Interface Module is designed for integration in the SCB Interface Control, SCB Media Control or ACC Control and enables the COVIDIEN ForceTriad Energy Platform to be controlled remotely with the KARL STORZ SCB control NEO system.

Prescription Use: X AND/OR Over-The-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111165